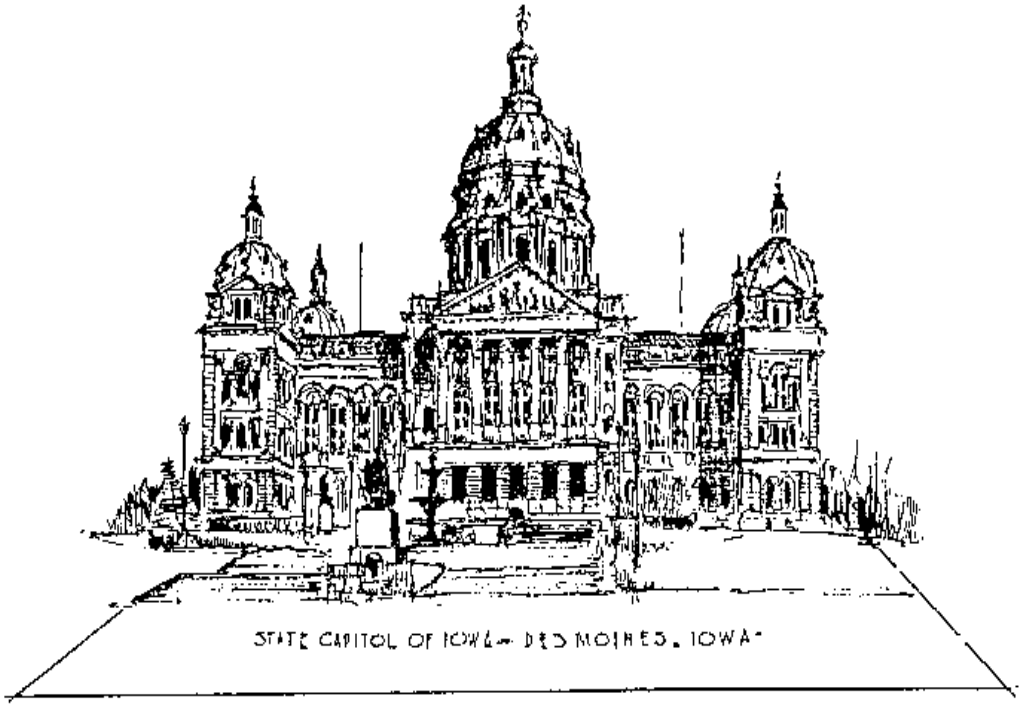
IOWA DEPARTMENT OF PUBLIC HEALTH

PORTABLE GAUGING DEVICE REGULATORY GUIDE



Iowa Department of Public Health
Bureau of Radiological Health
Radioactive Materials Section
Lucas State Office Building, 5th Floor
321 East 12th Street
Des Moines, Iowa 50319-0075

IDPH REGULATORY GUIDE FOR PORTABLE GAUGING DEVICES

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PORTABLE GAUGING DEVICES

1. INTRODUCTION

1.1 PURPOSE OF GUIDE

This regulatory guide describes the type and extent of information needed by the IDPH to evaluate an application for a portable gauge license and describe the byproduct regulations. An example of a portable gauging device is a moisture-density gauge that contains a gamma-emitting sealed source, Cesium-137, and a sealed neutron source, Americium-241: Beryllium.

The information in this guide is not a substitute for training in radiation safety or for developing and implementing an effective radiation safety program. You should carefully study this guide and all the regulations identified in the Iowa Rules and should then complete the application form, IDPH Form 299-0514. The IDPH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program.

1.2 APPLICABLE REGULATIONS

Regulations pertaining to this type of license are found in Chapters 38, 39, and 40 of the Radiation Machine and Radioactive Materials Rules. You may go to www.idph.state.ia.us and click on Health Protection and Environmental Health. Follow the links to the Bureau of Radiological Health. The regulatory guides can be found by further following the links to Radioactive Materials.

1.3 AS LOW AS IS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 641-40.1(3) states "...Every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA)." As an applicant, you should consider the ALARA philosophy in the development of work plans involving radioactive materials.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources.

The Radiation Safety Officer (RSO) and management are required to audit the by-product material program to ensure the continued safe use of by-product material. The RSO is also responsible for the day-to-day operations of the radiation safety program.

A model ALARA management program is contained in Appendix A to this guide. Applicants are required to consider the ALARA philosophy in the development of plans for radioactive materials.

2. FILING AN APPLICATION

You should apply for a license by completing form 229-0514, "Application for Radioactive Materials License." You should complete Items I through 5 and 14/15 on the form itself For Items 6 through 12, submit the information on supplementary pages. Each separate sheet or document should identify the item in the application to which it refers. All typed pages, sketches, and drawings should be on 8 1/2 X 11-

inch paper to facilitate handling and review, if possible. If larger drawings are necessary, they should be folded to 8 1/2 X 11 inches.

You should complete all items in the application in sufficient detail for the IDPH to determine that your equipment, facilities, training, experience, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the public in the IDPH offices. Do not submit proprietary information unless necessary. If submittal of such information is necessary, please clearly specify the proprietary information. Failure to do so may result in disclosure of propriety information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, submit the training and experience of individuals demonstrating their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should be submitted only if they are part of the emergency response plan. Submitting of dates of birth, social security numbers, and radiation dose information is required only if specifically requested by IDPH.

Retain a copy of your application because the license will be issued based on the statements and representations in your application and any supplements to it as well as the requirements in the regulations. The statements and representations become enforceable as if they were regulations.

3. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested on IDPH Form 229-0514. The appendices to this guide serve to

- provide additional information on certain subject areas;
- provide a model procedure the applicant may adopt in response to an item on the application form; or
- provide an outline the applicant may use to develop a procedure for review by the IDPH staff.

If you have specific questions after careful review of this guide, contact the IDPH material licensing staff at Iowa Department of Public Health, Radioactive Materials Section, Lucas State Office Building, 5th Floor, 321 East 12th Street, Des Moines, Iowa 50319-0075, or call 515-281-3478.

ITEM 1.a. -- APPLICANT'S NAME AND MAILING ADDRESS

The applicant should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material is used as specified in Item 1.b.

ITEM 1.b. -- LOCATIONS OF USE

You should specify each location of storage or use by the street address, city, and state or other descriptive address (such as 5 miles east on Highway 10, Anytown, Iowa) to allow us to easily locate your facilities. A post office box address is not acceptable. Specify whether a location is for storage, use, or both for sources and devices.

If you will conduct operations at temporary job sites, you should specify "temporary job sites in Iowa."

ITEM 2. -- PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer informational questions only about the application. This individual, usually the Radiation Safety Officer (RSO) or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the IDPH if this individual changes. Unless the contact person is the RSO, a contact change is for information only. It would not be considered an application for a license amendment.

Any requests from the IDPH concerning additional commitments, procedures, or for changes to the application will be addressed to the CEO or President with a copy to the RSO. The CEO can designate a different person if the authorization to make commitments on behalf of the licensee if the CEO or President provides that authorization in writing to IDPH.

ITEM 3. -- LICENSE INFORMATION

For a new license, amendment to a license or renewal of an existing license, check the appropriate block. Provide the license number where indicated for amendments or renewals.

ITEM 4. -- INDIVIDUAL USERS - THEIR TRAINING AND EXPERIENCE

Employees who will use the gauges under the supervision of a responsible individual named in Item 4 do not need designation by name. Provide information in 4.1 or 4.2 below.

4.1. If gauge users will receive training in a gauge manufacturer's course, provide the following:

1. A commitment that before permission is granted to an individual to use a gauge, they will have:
   (a) successfully completed a gauge manufacturer's course,
   (b) received copies of, and been trained in, the applicant's operating and emergency procedures, and
   (c) been designated as an authorized user by the RSO.

2. For each individual trained after you have made the above commitment, you should maintain records demonstrating that the individual meets the requirements of 1.a above. These records should be maintained until three years after the individual ends employment.

4.2. If users will receive training in an alternative course (other than the manufacture's course), provide the following:

1. You may commit to providing the training outlined in Appendix B Part I of the IDPH Regulatory Guide for Portable Gauging Devices or you should provide a description of the course (including topics covered and amount of time devoted to each topic).

2. Name and qualifications of each instructor. Proof of completion of the device manufacturer's training program or equivalent: See Appendix B, Part 2.

3. a. A commitment that before using the gauge, each individual will have successfully completed the course above received copies of and has been trained in operating and

emergency procedures. The individual will then be designated as an authorized user by the RSO.

b. Maintain records demonstrating that the individual successfully completed the training course. The records should indicate the course content and instructor qualifications, the operating and emergency procedures given, and that the user was designated as an authorized user by the RSO. These records should be maintained until three years after the individual ends employment.

4.3. 1. In addition to 4.1 or 4.2 above, submit a commitment that refresher training will be provided to all gauge users at intervals not to exceed one year. The RSO or an instructor whose qualifications are those described in Part II of Appendix B should conduct the training. This training should include review of emergency procedures, DOT requirements, changes in applicable regulations or license conditions, and deficiencies identified during the performance of annual audits of the radiation safety program.

2. Maintain records of the annual refresher for at least three years. The records should include the date of the training, the instructor, list of attendees, and topics covered.

ITEM 5. -- RADIATION SAFETY OFFICER (RSO)

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience in radiation protection and in the handling of gauges. Even if you employ a consultant to assist the RSO, you are still responsible for the radiation safety program as required by the license.

The RSO needs independent authority to stop operations considered unsafe. The RSO also needs sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used only by authorized individuals and in a safe manner. The RSO's duties and responsibilities should include those areas listed in Appendix C. You should commit to Appendix C or its equivalent.

ITEM 6. -- RADIOACTIVE MATERIAL

1. Identify each radioisotope that will be used in the gauging device.
2. Identify the manufacturer and model number of each sealed source used in the gauging device.
3. Specify the amount of radioactive material that will be in each sealed source in Becquerels or curies.
4. Identify the manufacturer and model number of the gauging device in which the sealed sources will be used.
5. List any survey meter or calibration source not exempted under 39.4(3)"c"(9).

You should consult with your proposed supplier for this information to be sure that your sources and devices conform to the sealed source and device designations registered with the US Nuclear Regulatory Commission (NRC) or an Agreement State.

NOTE: It is the practice of IDPH to provide flexibility in the number of identical sealed source/device combinations you may want to possess at any one time. Therefore, it is not necessary for you to specify the number of identical source/device combinations. You will need to amend your license before you obtain a gauge other than those listed in Item 6.

ITEM 7. -- PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

Specify the purpose for which the gauging device you want to possess will be used. For example, a moisture/density gauge is normally used for measuring moisture and density of construction material. In order for gauging devices to be used safely, the device should be used only for the purposes for which the gauge was designed and in accordance with manufacturer's recommendations for use.

Also, specify whether the device will be lowered into the ground more than the one (1) to three (3) feet common for most surface measurements. If you plan to make measurements at depths exceeding three (3) feet, you will need appropriate provisions in your operating and emergency procedures to reduce the probability of the device becoming lodged in the hole and to recover a "stuck" source. You are required to notify the IDPH if a device becomes lodged in a hole and it becomes apparent that recovery efforts will be unsuccessful.

ITEM 8. -- INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

Submit a description or chart of the overall organization pertaining to the gauge program that specifies the name and title of each individual who has responsibility for management or supervision of the program.

ITEM 9. -- TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

A trained "responsible individual" should always be physically present at your facility when devices are in use. It is not necessary to name each employee who will work under the supervision of a "responsible individual" named in Item 4. As a minimum, however, such employees would receive training and instructions in the operation and use of your device. Describe your training program for individuals who will work under the supervision of a "responsible individual."

Awareness training should also be provided to all employees that may interface with the radiological program. The purpose of this training is to inform personnel of the presence of radioactive material and to address any of their concerns. The training need not be involved but should commensurate with the potential hazard(s). You should list the personnel that will receive the training (use positions rather than individual names, e.g., secretarial staff, maintenance personnel, etc.). Commit to providing such training to all appropriate individuals.

ITEM 10. -- FACILITIES AND EQUIPMENT

641-39.4(25)"b" states that an application will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Therefore, you should provide the following information concerning your equipment and facilities:

1. A diagram that shows where the gauge will be stored when not at field locations.
2. The security measures to be taken during storage when not at field locations.
3. The security measures taken when stored in the field.
4. If the proposed permanent facility is under construction, or is planned for construction, include the estimated completion date.

Iowa Administrative Code (IAC) 641-40.55(5) requires that “each licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee”. This applies to permanent storage locations, temporary storage locations and during transportation.

You should keep in mind that the device needs to be in storage or physically watched by an authorized user at all times. It is not acceptable for a device to be chained to a post or left lying unattended at the place of use during lunch or breaks, because the device would then be accessible to unauthorized persons.

Provide diagrams of the facility that include the building, the proposed restricted area(s). Indicate the use of the adjacent areas (e.g., storage, hallway, etc.). Include the spaces above and below the restricted areas.

If any proposed permanent facility is a private residence, confirm that the use of the gauge does not conflict with local codes or zoning laws. Provide commitments that restricted areas do not include residential quarters and explain how radiation levels in unrestricted areas will be controlled and monitored to comply with Chapter 40.

Any change in permanent storage locations that result in a change of physical address requires an amendment to the license. The amendment must be approved by IDPH prior to use of the location.

ITEM 11. -- RADIATION SAFETY PROGRAM

You, as the licensee, are responsible for the conduct of your radiation safety program and for all actions of your employees.

11.1. -- PERSONNEL MONITORING EQUIPMENT

All your personnel should wear a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD) when they use the device. State the type of personnel monitoring equipment you will use, the name and address of the supplier, and the frequency at which the personnel dosimetry is exchanged. The changes should be made at intervals not to exceed one month for film badges and three (3) months for TLDs and OSDs.

Personnel exposed on an occasional basis will not normally be issued exposure monitors.

11.2. -- RADIATION DETECTION INSTRUMENTS

You do not need to have a radiation survey meter during routine use if you have made the commitment that personnel will wear a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD) when using the device. IDPH must be contacted immediately for timely evaluation of any incident.

If you plan to perform gauge servicing that requires removal of the source from its shielded position or removal of the source rod from the gauging device, you must have a survey meter that is calibrated annually. Provide the manufacturer name, model number, and range of the survey instruments being used. As an example:

Manufacturer	Model Number	Range
Geotronics Industries	OMG-12	0.01 - 50 mr/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mr/hr

If you plan to send your survey instruments to a private contractor for calibration, provide the name, address, and license number of the provider. If you plan to perform your own calibration, request the regulatory guide on survey instrument calibration from the IDPH.

Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery charges are not considered "servicing."

State that before using the survey meter, you will check the response of the instrument with a check source and, if the meter does not respond properly, you will not use the meter until it is repaired and operable.

11.3. -- LEAK-TESTING

As a licensee, you must perform according to 641-40.32(2). The IDPH requires tests to determine whether or not there is any leakage from the radioactive source in the device. The leak test should be performed at 6-month intervals unless otherwise authorized by your license.

The options for leak testing are:

1. Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.
2. Use a commercial leak-test kit. You take the smear and send the smear to the kit supplier, who reports the results to you.
3. Perform the entire leak-test sequence yourself, including the smears and measurement.

For Option 1, specify the name, address, and license number of the consultant or commercial organization.

For Option 2, specify the name, address, and license number of the leak test kit supplier and company who will analyze the samples. Commit to Appendix D.I or submit your own procedures.

For Option 3, describe the procedure for taking the test sample. Indicate the instrumentation that will be used for measurement. An instrument capable of making quantitative measurements should be used. Hand-held survey meters will not normally be considered adequate for these measurements. Include a sample calculation for conversion of the measurement data to microcuries. You should also specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in your application. Commit to Appendix D or submit your own procedures.

11.4. -- MAINTENANCE

You should state that any maintenance you will perform (such as cleaning) will always be done with the radioactive source in the safe shielded position. You may not do any maintenance unless the source is safely shielded.

To take the radioactive source out of the device, you must have special training and procedures, use a radiation survey meter, and take appropriate radiation safety precautions. If you plan to remove the source from the device for exchange or maintenance, your license must specifically authorize those procedures. Review Appendix E and submit the requirements listed there.

11.5. -- TRANSPORTATION OF DEVICES TO FIELD LOCATIONS

It is your obligation to obtain a copy of the DOT regulations on transportation of radioactive materials. The requirements for package labeling are in subpart E of 49 CFR Part 172 of the DOT regulations. General requirements for shipping and packaging radioactive material are in Subpart I of 49 CFR Part 173 of the DOT regulations. The address to write for a copy of these regulations is:

US Government Bookstore
120 Bannister Road
Kansas City, MO 64137
(816) 765-2256

You should state in your application that packaging and transport of the device will be carried out in accordance with the applicable DOT regulations.

11.6. -- OPERATING AND EMERGENCY PROCEDURES

Commit to providing the manufacturer's operating and emergency procedures; commit to the procedures in Appendix F; or, submit your procedures to the IDPH for review. You should cover these topics in your procedures:

1. Use of personnel monitoring.
2. Use of the device. Step-by-step procedures for the use of the device.
3. Storage of the device. (See the commitment in ITEM 10.)
4. Transportation. Procedures for transporting devices to and from work sites.
5. Emergency procedures.

See Appendix F for sample operating and emergency procedures.

You should state on your application that you will provide the operating and emergency procedures to each person who uses the device.

11.7. -- INVENTORIES

State that you will conduct inventories at intervals not to exceed six (6) months, to account for all sealed sources and gauges received and possessed under your license. You should maintain records of the inventories for at least five (5) years from the date of the inventory. The records should include the radionuclide and amount of material in each source, the manufacturer's name, model number and serial number of each gauge, the location of each, and the date of the inventory.

11.8. -- ANNUAL AUDIT OF RADIATION SAFETY PROGRAM

40.10(3) requires an annual audit of your radiological program. As part of an audit program, applicants should consider performing unannounced audits of their authorized users in the field to determine that proper radiation safety and operating procedures are being followed.

Once problems are identified, it is essential that they be promptly corrected. IDPH will review a licensee's audit program and determine if corrective actions are timely, thorough, and sufficient to prevent recurrence. Normally, IDPH will not cite violations identified and corrected by the licensee before an inspection. IDPH encourages licensees to regulate their own compliance.

An audit program for a portable moisture/density gauge should include a review of:

- ✓ leak test records and procedures
- ✓ inventory records
- ✓ training
- ✓ the operating and emergency procedures
- ✓ the use of the device by employees
- ✓ shipping papers and transportation procedures
- ✓ survey instrument calibration records and procedures (if applicable)

ITEM 12. -- WASTE MANAGEMENT

641-40.70(136C) specifies the requirements for disposal of licensed material. Because of the nature of the licensed material contained in gauging devices, your only option for disposal is to transfer the radioactive material to an authorized recipient as specified in paragraph 641-40.70(1)"a". You should state that disposal will be by transfer to a licensee specifically authorized to possess the radioactive material.

Authorized recipients are the original suppliers of the gauges, a commercial firm licensed by the NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of your licensed material.

ITEM 13. -- LICENSE FEES

1. An application fee paid in full is required by 641-38.8(2) for all new licenses and amendments. Fee information is available in the above rule or our web site at www.idph.state.ia.us. An application received without a fee or with an inadequate fee may be returned to you. Fees for processed applications are not refundable. Make check or money order payable to the IDPH.

2. An annual fee will be assessed based on the license category and is due by September 1st of each year. IDPH sends a billing invoice in July of each year for the annual fee.

3. Review 39.4(26) “Financial Assurance and Recordkeeping for Decommissioning.” Submit financial assurance as described or provide information that exempts the facility.

ITEM 14/15 -- CERTIFICATION

A senior partner, the president, director or chief executive officer, must sign the application. Identify the title of the office held by the individual who signs the application.

If the senior partner, president, director, or chief executive officer wishes another person other than himself to sign the application, a delegation of authority must be enclosed. The delegation of authority should state that the person signing the application has authority to commit the facility to the conditions of the application and any amendments submitted later.

4. AMENDMENTS TO A LICENSE

A licensee must receive a license amendment before changing the scope of the program such as changing the Radiation Safety Officer or adding a different gauge. See 641-39.4(35). An application for a license amendment may be prepared either on the application form 229-0514 or in letter form, must be signed by the person delegated in Item 14/15, and must include the appropriate amendment fee. References to previously submitted information and documents should be clear and specific and should

identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience. The qualifications of the new responsible individual should be equivalent to those specified in Item 4 of this guide.

5. RENEWAL OF A LICENSE

Licenses are issued for a period of five (5) years. An application for the renewal should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before the final action on the application has been taken by the IDPH as provided for in paragraph 641-39.4(34). The application for renewal should not reference material that was previously submitted.

If you do not wish to renew your license and cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating IDPH regulations that do not allow you to possess licensable material without a valid license.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating IDPH regulations that do not allow you to possess licensable material without a valid license.

6. IMPLEMENTATION

The information in this regulatory guide is guidance, not requirement. The IDPH reviews each application to ensure that users of byproduct material are capable of complying with IDPH's regulations. This guide provides one set of methods approved by the IDPH for meeting the regulations and represents the minimum acceptable standards.

7. INSPECTIONS

IDPH conducts initial inspections of new radiological programs between six months and one year after licensed material is received and operations have begun. Subsequent routine inspections of licenses are normally scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency, which is indicated in the IDPH Radioactive Materials Fee Schedule.

APPENDIX A

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix A to the IDPH Regulatory Guide for Portable Gauging Devices." Submit a signed copy of section 5 of this appendix.

If you prefer, you may develop your own ALARA program for IDPH review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Iowa Rules. Say on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program and a signed copy of section 5 of this appendix.

ALARA PROGRAM

1. MANAGEMENT COMMITMENT

   a. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution.

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far as below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. RADIATION SAFETY OFFICER COMMITMENT

   a. Annual and Quarterly Review

      (1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
      (2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of section 4 of this appendix.

b. Education Responsibilities for ALARA Program

The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
(3) Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

d. Reviewing Instances of Deviation from Good ALARA Practices:
The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

3. AUTHORIZED USERS COMMITMENT

a. New methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult the RSO during the planning stage before using radioactive materials for new uses.
(2) The authorized user will review each planned use of radioactive materials to ensure that uses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals
(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

4. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION DOSES[1]

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

[1] IDPH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

TABLE 1 Investigational Levels		
	Investigational Levels (mrems per month) Level I	Level II
1. Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
2. Skin of whole body, extremities	2000	4000
3. Lens of eyes	600	1200

The RSO will review and record on IDPH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter as required by 641-40.100. The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the investigational Level I.

b. Personnel doses equal to or greater than Investigation Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required. The RSO will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's Form IDPH 588-2834 “Occupational Exposure Record for Monitoring Period” and 588-2833 “Cumulative Occupational Exposure History” or its equivalent.

d. Re-establishment of investigational levels to levels above those listed in Table I.

In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

The RSO and management will review the justification for and should approve all revisions of investigational levels.

5. SIGNATURE OF CERTIFYING OFFICIAL[1] Sign and submit as part of Appendix A.

I hereby certify that this institution has implemented the ALARA Program as set forth above.

_____
Signature

_____
Name (Print or type)

_____
Title

[1]The person who is authorized to make commitments for the administration of the institution (e.g., CEO, president, etc.).

APPENDIX B

CRITERIA FOR ACCEPTABLE TRAINING COURSES FOR PORTABLE GAUGE USERS

You may use the following model procedure for training of portable gauge users. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for training that was published in Appendix B to the IDPH Regulatory Guide for Portable Gauging Devices." Manufacturer training may be used as an alternative. It should include the features indicated below. If you choose to use manufacturer training, say on your application, "We will establish and implement manufacturer training for all gauge users."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Iowa Rules. Say on your application, "We have developed a training program for your review that is appended as Appendix B," and submit your procedure.

Part I: Criteria for acceptable training courses for portable gauge users

1. Courses are at least 8 hours in length
2. Course provides instruction in the following topics (the hours next to each topic are suggestions):
   a. Radiation physics (.5 hour)
      Atomic and subatomic structure
      Radioactivity and types of radiation
      Sources of radioactivity
      Isotopes and periodic table
      Units of radiation measurement and half-life
   b. Radiation safety (1.0 hour)
      Biological effects of radiation
      Occupational dose limits
      ALARA
      Methods to reduce dose
      Personnel monitoring
   c. Regulatory requirements (1.5 hours)
      Licensing
      Storage of licensed material
      Constant control and surveillance of radioactive material not in storage
      Personnel monitoring
      Leak testing
      Inventory
      Maintenance
      Operating and emergency procedures
      Audits
      Record keeping
      Reciprocity
      Disposal
      Incidents
   d. Transportation (.5 hour)
      Transportation of licensed material in vehicles
      Shipping by common carrier
      Requirements in 10 CFR 71.5, 49 CFR, and Iowa Chapter 39.5
   e. Gauge theory, operation, and field training (3.5 hours)

f. Written test and test review (.5 hour)

3. Successful completion of the course requires obtaining a score of at least 80% on a closed-book test consisting of at least 50 questions that have not been provided to the students before the test.
4. Course instructors meet the qualifications outlined in Part II below.

Part II: Criteria for qualifications for instructors of portable gauge users

Each instructor who trains individuals as portable gauge users should have successfully complete a course that meets the criteria in Part I above, and have at least 32 hours of hands-on experience in the use of portable gauge devices.

APPENDIX C

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

You may use the following model procedure to make commitments for your RSO. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for RSO that was published in Appendix C to the IDPH Regulatory Guide for Portable Gauging Devices."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Iowa Rules. Say on your application, "We have developed an RSO procedure for your review that is appended as Appendix B," and submit your procedure.

MODEL PROCEDURE

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include:

1. Ensure that licensed material possessed is limited to the kinds, quantities and gauge holders listed on the license.
2. Ensure that individuals using gauges are properly trained and are designated by the RSO. Ensure that they receive refresher training at least annually. Ensure that they are informed of all regulatory changes and deficiencies identified during annual audits or IDPH inspections.
3. Ensure that personnel monitoring devices are used as required. Review in a timely manner all reports of personnel exposures.
4. Ensure that gauges are properly secured against unauthorized removal at all times when gauges are not in use.
5. Ensure that proper authorities are notified in case of accident, damage to gauges, fire, or theft.
6. Ensure that audits are performed at least annually to ensure that:
   (a) The licensee is abiding by IDPH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, transportation, and use by approved users);
   (b) The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA (see IDPH Rules, Chapter 40); and
   (c) The licensee maintains required records with all required information (e.g., records of personnel exposure, receipt, transfer, and disposal of licensed material, gauge user training) sufficient to comply with IDPH requirements.
7. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least three (3) years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).
9. Ensure that all incidents, accidents, and personnel exposure to radiation more than ALARA or Chapter 40 are investigated and reported to IDPH within the required time limits.
10. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
11. Ensure that licensed material is disposed of properly.
12. Ensure that the facility has up-to-date copies of IDPH’s regulations, completing a review of new or amended IDPH regulations, and revising licensee procedures, as needed, to comply with IDPH regulations.
13. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to IDPH in the licensing process.

APPENDIX D

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

You may use the following model procedure to leak-test sealed sources. If you follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix (D. I and/or D.2) to the IDPH Regulatory Guide for Portable Gauging Devices."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Iowa Rules. State on your application, "We have developed a leak-test procedure for your review that is appended as Appendix (D.1 and/or D.2)," and submit your leak-test procedure.

D.1. MODEL PROCEDURE FOR TAKING TEST SAMPLES

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

    a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
    b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
    c. If you are testing radium sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak-test period.

D.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES

(For Option 3 of Item 11. 3)

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect the levels in 40.32. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a scintillation detector with either a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source. The source activity should be certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.

3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or disposed of in accordance with IDPH rules.
7. Record model number and serial number (if assigned) of each source tested, radionuclide and estimated activity, measured activity of each test sample in microcuries, description of method used to test each sample, date of test, and signature of RSO. Maintain record for five (5) years.

APPENDIX E

EXTENDED MAINTENANCE

If you are considering performing maintenance or cleaning of gauges that requires the removal of the radioactive source or source rod from the shielded position, you should keep in mind the radiation levels you may encounter. A typical moisture-density gauge contains 10 millicuries of Cesium-137 and 40 millicuries of Americium-241. In about 9 minutes an unshielded Cesium-137 source of this activity can deliver 5 rem to a worker's hands or fingers (extremities), assuming the extremities are I centimeter from the source. The threshold for extremity monitoring is five rem per year.

Thus, to perform extended maintenance, you should have special training, authorization on your license, follow special procedures, use a radiation survey meter, use special shields, use special personnel monitoring devices, and take appropriate radiation safety precautions. Accordingly, provide the following information:

1. Type of work to be performed
   Describe the types of work, maintenance, or cleaning that you wish to perform that necessitate removal of the radioactive source from the shielded position or the removal of the source rod from the device. For each type of device, specify the manufacturer's name and the model number of the gauge.

2. Training and experience
   List the individuals who will perform extended maintenance and describe their training and experience in performing the maintenance. Individuals are considered on a case-by-case basis. For each individual that will perform extended maintenance, indicate
   - all radiation safety courses the individual has taken;
   - the amount of hands-on experience the individual has had performing extended maintenance (include the manufacturer's name and model of the gauge in addition to the type and frequency of extended maintenance performed); and
   - any additional factors to document that the individual is competent to perform extended maintenance safely.

3. Handling procedures
   Submit your procedures for safe handling of the radioactive source while the source is outside the gauge. Your procedures should specify that
   - the source rod will be handled only at the end opposite to the source end;
   - the source end will immediately be placed in a shielded container (e.g., lead shield);
   - unauthorized individuals will not be allowed into the areas where extended maintenance is performed;
   - containers shielding the source will be labeled "Caution Radioactive Material";
   - the source will be under the constant surveillance of an authorized user when not in storage
   - will be secured against unauthorized removal or access when in storage;
   - the manufacturer's instructions and recommendations for performing extended maintenance will be followed.

   Indicate where the source rod is located after it has been removed.

4. Personnel monitoring
   Describe how you will ensure that radiation exposure to individuals performing extended maintenance will not exceed Chapter 40 limits. An acceptable response is that individuals performing extended maintenance on gauges will always wear both whole body and extremity monitoring devices. Like the whole body devices, extremity monitoring devices will be exchanged at least quarterly.

5. Survey instrumentation

If you have already provided detailed information on survey instruments in response to previous items, state "See response to item ---." Otherwise, list the type and ranges of survey instruments you will have available, state the frequency of calibration, and state who will perform the calibration. Include how you will ensure that the survey instrument is working properly.

For example, you may state that a survey instrument capable of measuring between 0.1 millirem per hour and 100 millirem per hour will be used to perform the surveys. You must also confirm that the survey instrument will be calibrated annually by the manufacturer. In addition, you may state that, before each use of the instrument, you will check the response of the instrument with a dedicated check source that was supplied with the instrument. You should commit that, if the instrument does not respond properly, you will not perform extended maintenance on the gauges until the survey instrument is repaired and operable or until you obtain an operable instrument.

6. Surveys

Describe how you will ensure that radiation levels in areas where extended maintenance will take place do not exceed Chapter 40 limits. For example, you may

- commit to performing surveys with a survey instrument (as describe above),
- specify where and when surveys will be conducted during extended maintenance, and
- commit to maintaining records of the survey for three (3) years from the date of the survey, as required by 40.82 of the Iowa Rules. The survey record should include the name of the person who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements,

APPENDIX F

SAMPLE OF STANDARD OPERATING AND EMERGENCY PROCEDURES

You may use the following sample of operating and emergency procedures. If you follow the sample procedures, you may say on your application, "We will establish and implement the model procedures for operating and emergency procedures that was published in Appendix F to the IDPH Regulatory Guide for Portable Gauging Devices."

You may develop your own procedures for review. If you do so, you should consider for inclusion all the features in this sample and carefully review the requirements of the Iowa Rules. State on your application, "We have developed standard operating and emergency procedures for your review that are appended as Appendix F" and submit your procedures.

A copy of the Operating and Emergency Procedures should be provided to all users.

SAMPLE PROCEDURES

Operating procedures

1. Before removing the gauge from its place of storage, check to make sure that the gauge source rod is in the shielded, locked position, then lock the transport case if possible.
2. Sign the gauge out in a logbook, stating the dates of use, names of the authorized users who are responsible for the gauge, and the temporary job sites where the gauge will be used.
3. Never leave the gauge unattended.
4. Follow all applicable DOT requirements when transporting the gauge.
5. Do not touch the source rod with your fingers, hands, or any part of your body, and always make sure the source rod is in the shielded position after each measurement is made.
6. Always wear your assigned personnel-monitoring device (dosimeter) when using the gauge.
7. Never wear another person's dosimetry.
8. Never store your dosimetry near the gauge.
9. Always keep unauthorized persons away from the area where the gauge is to be used.
10. Always maintain constant surveillance and immediate control of the gauge when it is not in storage.
11. To make gauges more visible to operators of heavy equipment at construction sites, "stake and flag" each gauge, being sure that the flags are tall enough to be seen by heavy equipment operators.
12. Never look under the gauge when the source rod is being lowered into the ground.
13. After each measurement, return the source to the shielded position and lock it there.
14. When the gauge is not in use at a temporary job site, place the gauge in a secured storage location (e.g., locked in the trunk of a car or locked in a storage shed).
15. Return the gauge to its proper storage location at the end of the work shift.
16. When the gauge is returned to storage, indicate in the source logbook.

Emergency procedures

If the source fails to return to the shielded position or if any other emergency or unusual situation arises such as the gauge being struck by a moving vehicle, dropped, or in a vehicle involved in an accident:

1. Immediately secure the area around the gauge.
2. Prevent unauthorized personnel from entering the secured area.

3. If any heavy equipment is involved, detain the equipment until it is determined that there is no contamination present.
4. Notify management of the situation, calling company personnel (list name, work and home telephone numbers).
5. Follow the directions provided by the person contacted.
6. Management should:
    a. Arrange for a survey to be conducted using an appropriate radiation detection instrument as soon as possible by an approved person.
    b. Make necessary notifications to local authorities; notify the IDPH as required. Notification is required when gauges are lost or stolen, or damaged or involved in incidents that result in doses in excess of the dose limits in Chapter 40.
    c. Ensure reports to the IDPH are submitted in a timely manner.
    d. Review and adhere to the reporting requirements of 40.95, 40.96, and 40.97.

SUMMARY OF REVISIONS

Revision	Section	Description
PG-99 (01/27/99)	Item 11.8	Auditing Guidance
	Appendix G	Deleted the auditing checklist – incorporated into Section 11.8.
12/27/00	All	Format text. Changed address for Bureau of Radiological Health.
03/08/00	Item 4	Revised to clarify that applicant may commit to following Appendix B Part I.
	Item 9	Revised to clarify the training information requested and the personnel involved.
	All	Changes to the IDPH Regulatory Guide for Portable Gauging Devices
	Appendix G	Deleted
07/17/01	11.8	Deleted reference to Appendix G and added example of items that should be in an annual audit.
11/19/01	11.7	Revised inventory record retention from three years to five years.
01/18/02	Section 7	Added information concerning inspections.
03/13/03	Section 1.2	Replace the website address of the IDPH rules and publications.
07/01/05	All	Changed address for the Bureau of Radiological Health
03/19/08	Item 10	Added rule requirement of 641-40.55(5)
09/07/10	Sections 3.13 & 7	Removed references to renewal and inspection fees. Added reference to annual fee.